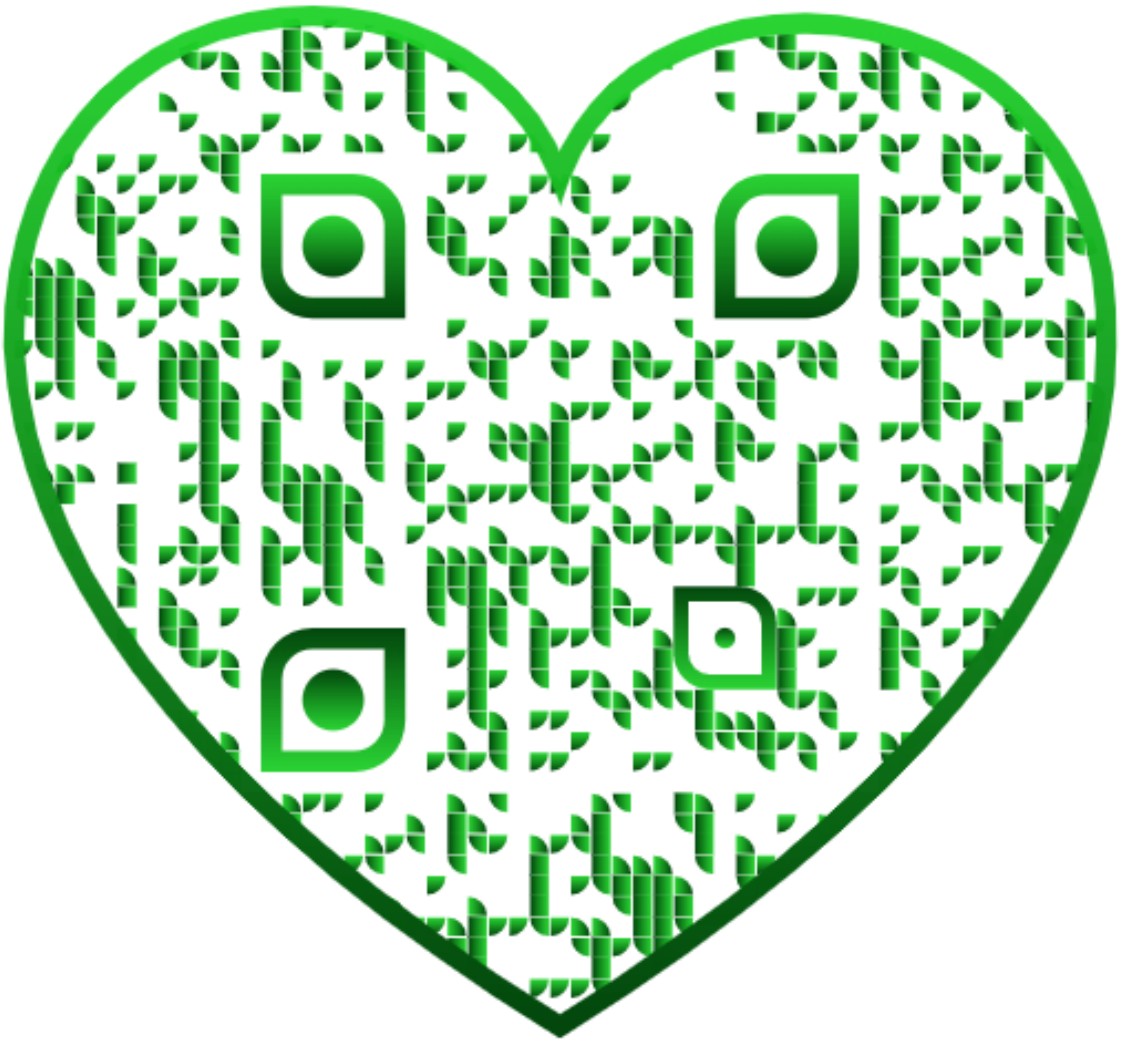
Chapter Two

Introduction To Pharmacoeconomics



Learning objectives

Upon completion of this chapter, you should be able to:

- Define Pharmacoeconomics
- Discuss the Goal of PE
- Identify Application of
- Discuss importance of PE studies
- Explain the importance of PE in healthcare decision making

Outline

- Introduction
- Definitions and objectives of PE
- Perspectives
- Importance/Applications of PE studies

Introduction

- Practitioners, patients, and health agencies face a multitude of challenges
  - As the development of new therapies seems boundless, while the money to purchase these cures is limited
- How does one decide which are the best medicines to use within restricted budgets?

- Purchasers and public agencies are demanding that health treatments be evaluated in terms of Clinical and humanistic outcomes against the costs incurred

INTRODUCTION (2): DEFINITION

- Pharmacoeconomics is description and analysis of the costs and consequences of pharmaceutical products and services and their impact on individuals, health care systems and society.
- It mainly works on the health economics which particularly focuses upon the costs and benefits of drug therapy.
- Powerful tool for evaluating products, therapies, & programs
- It is the part of health economics that focuses on the economic evaluation of pharmaceuticals.

Introduction (3)…definition

- PE studies serve to guide optimal healthcare resource allocation, in a standardized & scientifically grounded manner
- PE is an aid to decision making with strong potential to:
  - Mitigate the influence of marketing
  - Help set practice priorities
  - Enhances position of practitioner from payer's perspective

Introduction (4) ….Definition…

- Involves identifying, measuring, comparing the costs, risks, benefits of programs, services, or therapies & determining which produces the best health outcome for the resources invested
- Often referred to as “Health economics”
  - Especially when it includes comparison with non-pharmaceutical therapy or preventive strategies: Surgical interventions, medical devices, or screening techniques

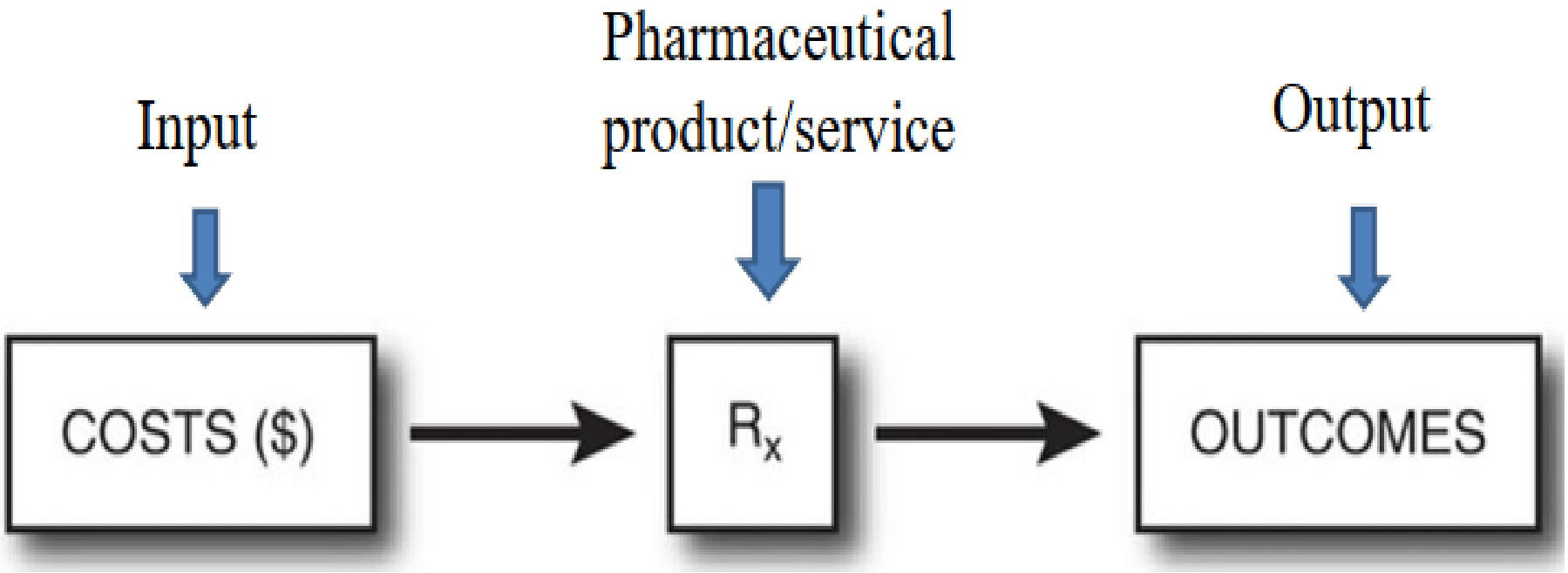
Objectives of PE

- The primary objective of PE is to maximize the net health benefit derived from the use of finite healthcare resources.
- Objectives of PE must originate within three dimensions when considering results and value of healthcare
  - Acceptable clinical outcomes
  - Acceptable humanistic outcomes
  - Acceptable economic outcomes

  Hence, PE addresses the Clinical, Economic, & Humanistic aspect of health care interventions.

  (often diagrammed as the ECHO Model)

Elements of full pharmacoeconomic evaluations



Inputs and Costs

Inputs – the value of the resources consumed to obtain and use the pharmaceutical product or service

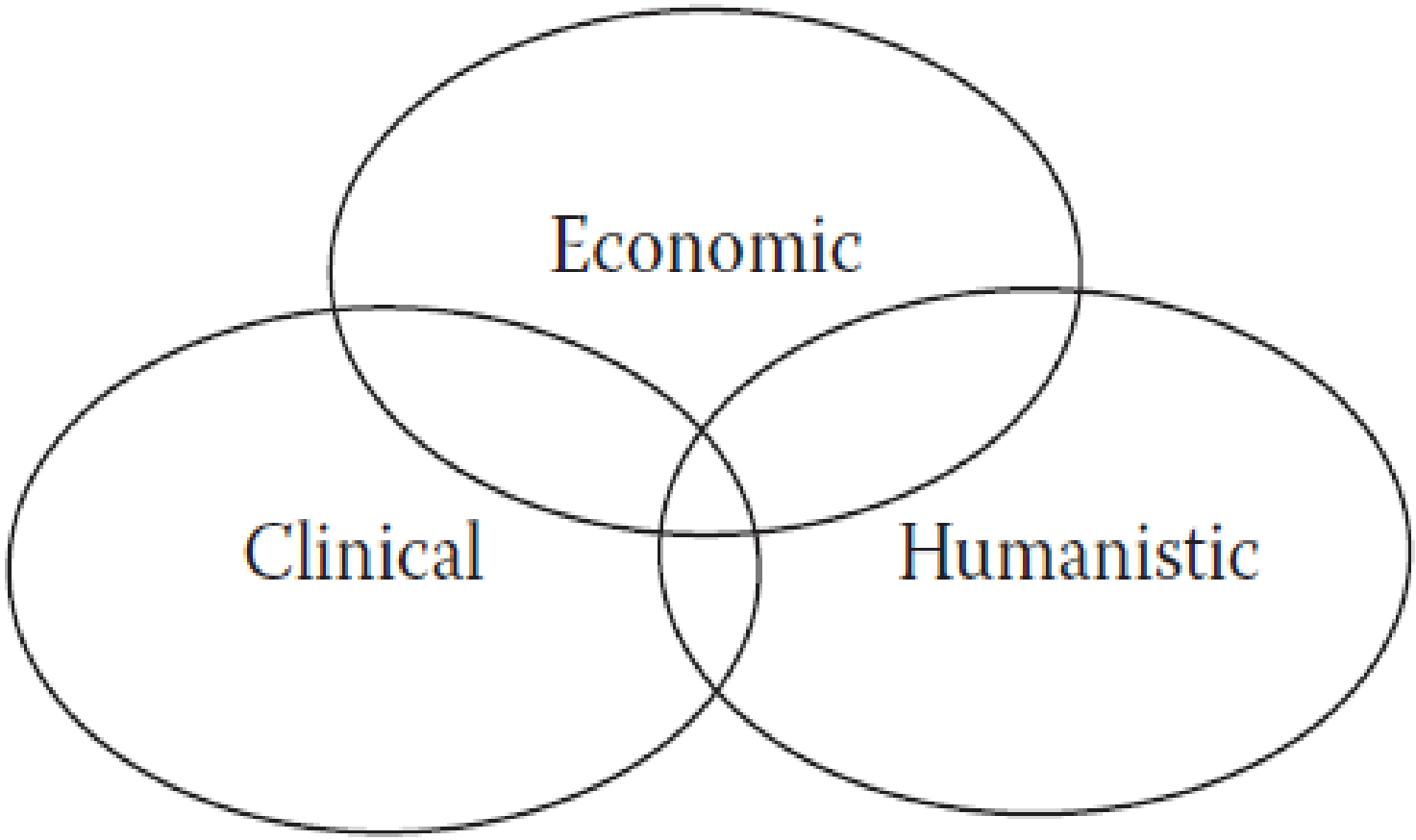
Costs - treatment costs can be grouped into four categories:

- Direct medical
- Direct nonmedical
- Indirect nonmedical, and
- Intangible costs
  (Discussed in chapter 3)

Outputs

- Output:
  - Health-related outcomes produced by the pharmaceutical product or service
  - The effects or consequences of drug therapy or the intervention
  - t/t outcome
- sources of treatment outcome data: randomized controlled trials and observational data sets, such as registries, administrative databases, clinical series and long-term epidemiological studies.
- Like costs, outcomes of medical care also can be grouped in to 3 categories: Clinical outcomes; Humanistic outcomes and Economic outcomes (ECHO)

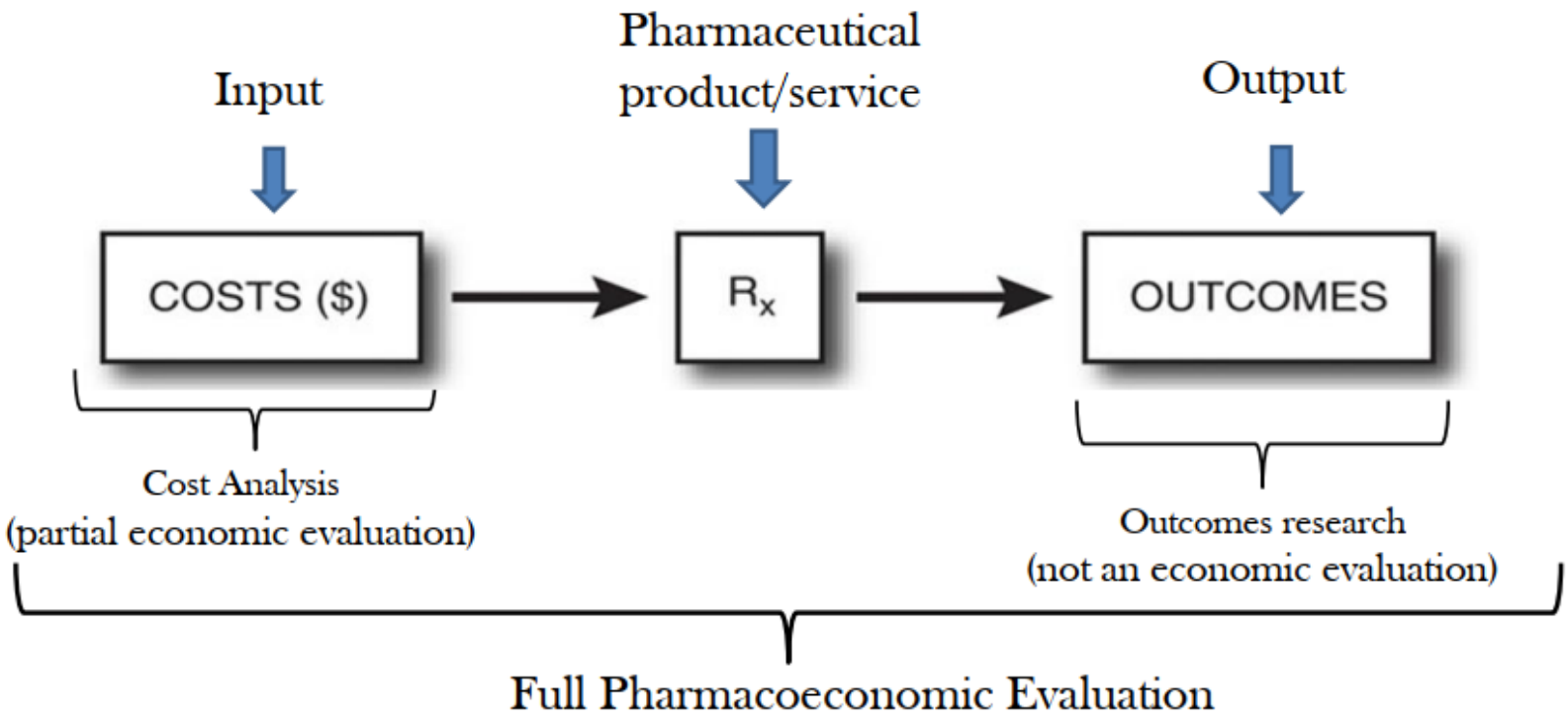
ECHO Model:
Economic, Clinical, and Humanistic Outcomes



ECHO Described

Outcome	Description
Clinical	Eradication of disease and physical survival Includes: Cure, comfort and survival
Humanistic	Quality of life, including physical, emotional, and social well being Includes: Physical, emotional, social function, role performance
Economic	Reduction in resource use or savings/cost avoidance Includes: Expense, saving, cost avoidance

Full Vs. Partial Evaluation method



Methods on PE

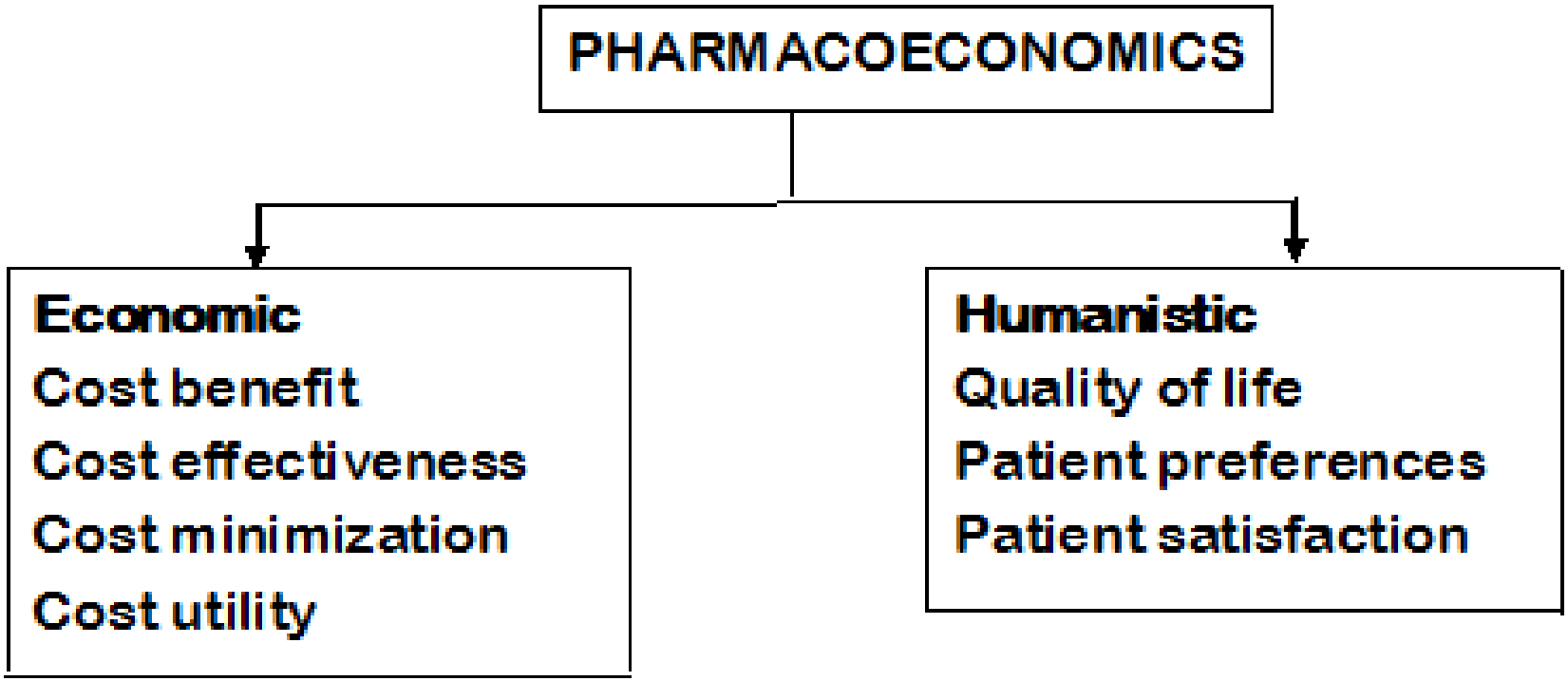
- There are four types of full pharmacoeconomic evaluation methods/tools used most commonly by healthcare practitioners:
  - ►Cost-minimization analysis (CMA)
  - ►Cost-effectiveness analysis (CEA)
  - ►Cost-utility analysis (CUA)
  - ►Cost-benefit analysis (CBA)
- The difference between the four pharmacoeconomic evaluation methods
  is how outcomes are measured/quantified

PE Evaluation Tools/Methods…

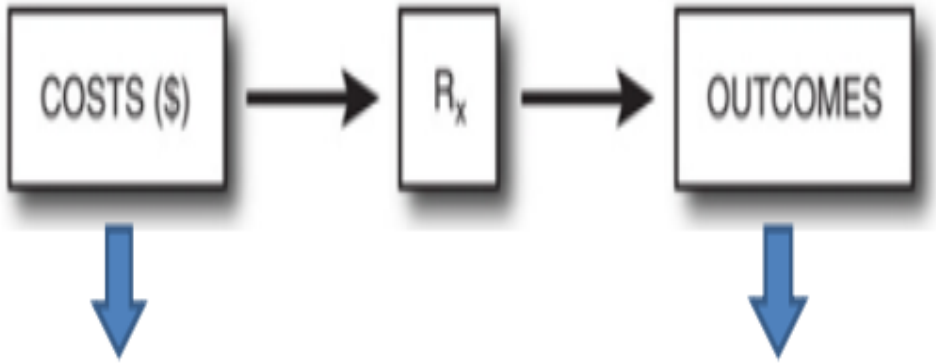
- Other PE techniques include
  - Cost of illness analysis (COI),
  - Cost-consequence analysis (CCA), etc.
- These methods or tools can be separated into two distinct categories: Economic and Humanistic evaluation techniques.
- The two common types of partial economic evaluations that involve the measurement of costs

Components of PE Studies

- 2 main components



Difference between methods



Type of Evaluation		
Cost-minimization	Monetary Units	Non specific (equivalent)
Cost-effectiveness	Monetary Units	Natural units (such as life years gained)
Cost-Utility	Monetary Units	Life years adjusted for quality of life (QALY)
Cost-Benefit	Monetary Units	Monetary Units

PE Evaluation Tools/Methods

- PE methods help
  - Document the costs and benefits of therapies and pharmaceutical services
  - Establish priorities for the therapeutic options
  - Helps in appropriately allocating resources in ever-changing health care settings

Summary of Pharmacoeconomic Methodologies

Method	Description	Application	Cost Unit	Outcome Unit
COI	Estimates the cost of a disease on a defined population	Use to provide baseline to compare prevention/ treatment options against	$$$	NA
CMA	Finds the least expensive cost alternative	Use when benefits are the same	$$$	Assume to be equivalent
CBA	Measures benefit in monetary units and computes a net gain	Can compare programs with different objectives	$$$	$$$
CEA	Compares alternatives with therapeutic effects measured in physical units; computes a C/E ratio	Can compare drugs/programs that differ in clinical outcomes and use same unit of benefit	$$$	Natural units
CUA	Measures therapeutic consequences in utility units rather than physical units; computes a C/U ratio	Use to compare drugs/programs that are life extending with serious side effects or those producing reductions in morbidity	$$$	QALY's
CCA	Measures multiple costs and outcomes without aggregating the two into a CE or CB ratio.	Examines whether the use of a drug produces an outcome that decreases costs and offsets the price cost of the new therapy	$$	Reported separately

Key: CBA = cost-benefit analysis; CEA= cost-effectiveness analysis; CMA= cost-minimization analysis; COI= cost of-illness evaluation; CUA= cost-utility analysis; CCA= cost consequence analysis

Applications of PE [1]

- One of the primary applications of PE in clinical practice today is to aid clinical and policy decision making
- Drug Therapy Evaluation
  - Selecting the most cost-effective drugs for an organizational formulary
  - Making a decision about an individual patient's therapy
  - Customizing a patient's pharmacotherapy
- Justify Pharmaceutical care Services
  - Determining the value of an existing service,
  - Estimating the potential worth of implementing a new service

Applications of PE [2]

- Justify Pharmaceutical care Services…
  - Capturing the value of a “cognitive” clinical intervention
  - Managed Care – protocols, guidelines, formularies
  - Physicians – individual patient treatment decisions, prescribing, payer-performance
  - Consumers – education, autonomy
  - Government – pricing, approval, formularies, policy
  - Institutions – protocols, guidelines, formularies
  - Pharmacists – formularies, protocols, guidelines, pharmaceutical care services or program evaluation

PE APPLICATIONS:

- The various applications of PE include:

►clinical decisions for individual patient treatment -(CEA & CUA)

►justification/evaluation of clinical services/programs – (CBA)

►formulary decision making – (CEA & CUA)

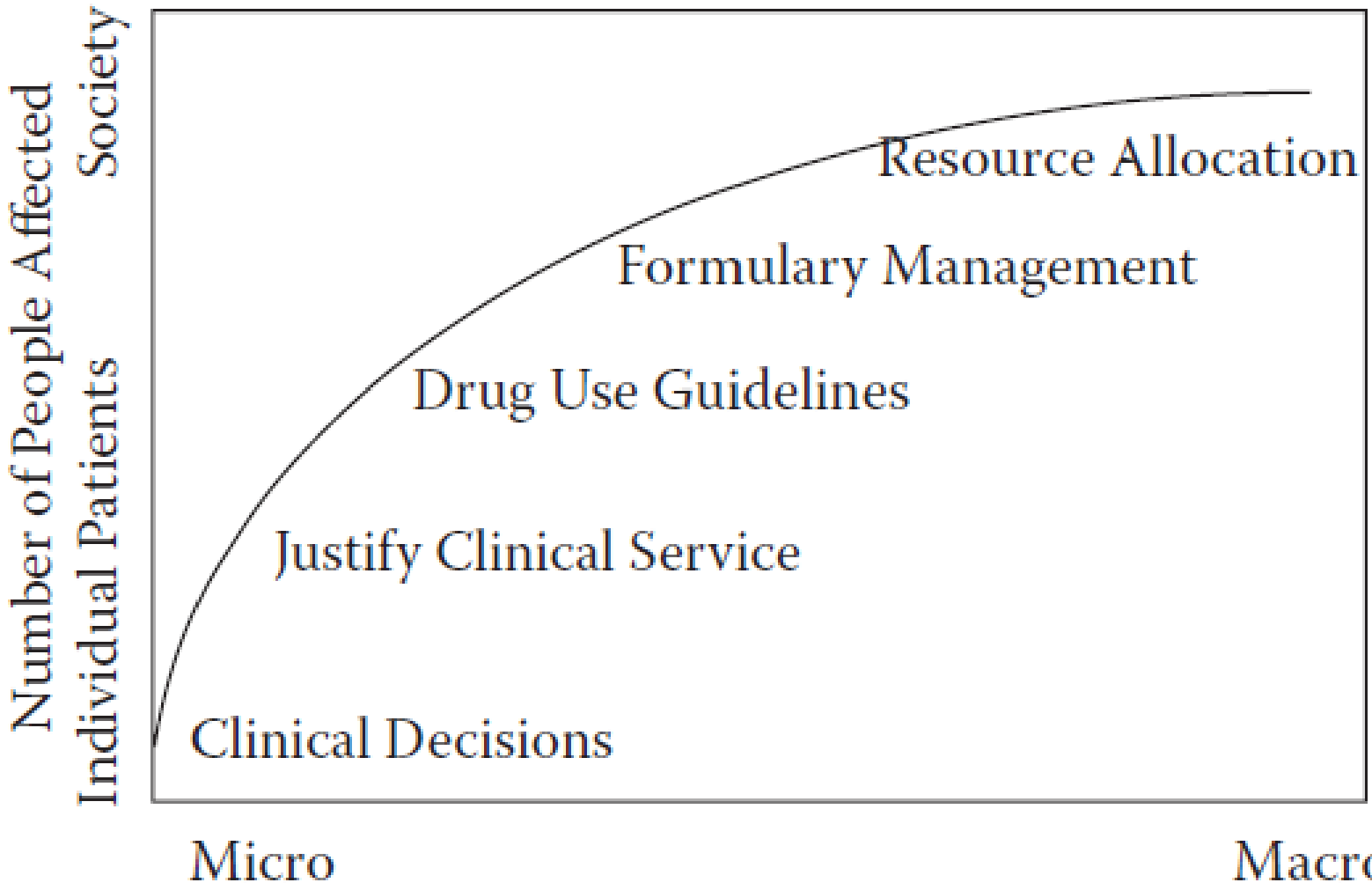
►to support drug policy - (CEA & CUA)

►resource allocation - (CEA , CUA & CBA)

Applications…

- Clinical decisions for individual patient treatment (two cancer treatments)
- Justify or evaluate clinical services/programs
- Formulary decision making (selection)
- To support drug policy (EML)
- Healthcare resource allocation decision making

Micro to Macro Applications with Pharmacoecomomics



Basic Value of Medical Care

- Evidenced by general trends:
  - Increased use of medical care and prescription drugs
  - Mortality rates of certain diseases have significantly declined
  - Mean length of hospital stay has also declined
- Despite this general evidence, few specific data regarding the actual costs and benefits attributed to drugs and medical therapies exist

Common Misconceptions When Applying PE Principles

- Cost-effective care is initially the **cheapest alternative** in a manner similar to other investments, least cost option may lead to greater costs downstream

- Cost-effective care is outcome that generates “biggest” effect in a manner to similar investments, smaller increments of outcome may be achieved at a lower overall cost

Need of Pharmacoeconomics

- Pharmacoeconomics identifies measures and compares the **cost and consequences** of pharmaceutical products and services,

- Describe the economic relationship involving the **cost and consequences of** drug research, drug production, distribution, storage, pricing and used by the people

PE Need.....continued

- In PE, the focus is frequently on both the cost (inputs) and consequences (outcomes)

Cost

- defined as the value of the resources consumed by a program or drug therapy of interest.
- Can be categorized as direct medical, direct nonmedical, indirect nonmedical, intangible, opportunity, and incremental costs

Consequence

- Defined as the effects, outputs, or outcomes of the program or drug therapy of interest

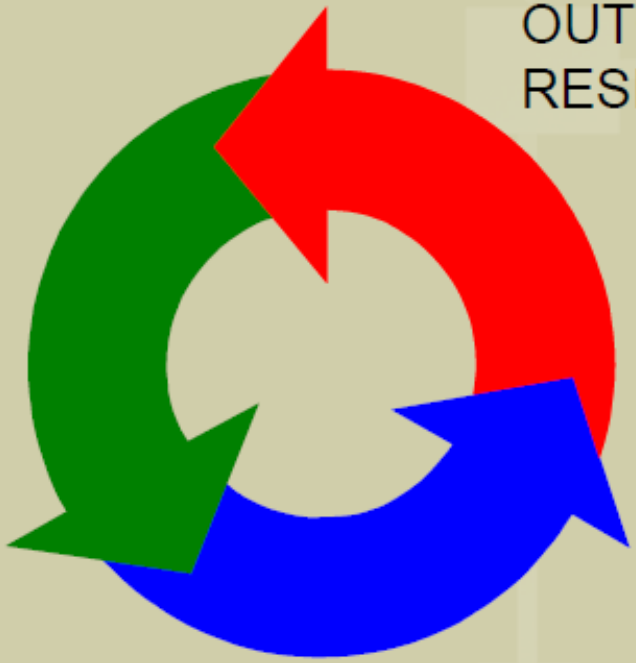
CONSEQUENCES

- Similar to costs, the outcomes or consequences of a disease and its treatment are an equally important component of pharmacoeconomic analyses.
- The manner in which consequences are quantified is a key distinction among pharmacoeconomic methods because the assessment of costs is relatively standard.
- Like costs, the consequences (or outcomes) of medical care also can be categorized.
- One approach is to separate outcomes into three categories: **economic, clinical, and humanistic.**
- ***Economic outcomes*** are the direct, indirect, and intangible costs compared with the consequences of medical treatment alternatives.

CONSEQUENCES

- ***Clinical outcomes*** are the medical events that occur as a result of disease or treatment (e.g., safety and efficacy end points).
- ***Humanistic outcomes*** are the consequences of disease or treatment on patient functional status or quality of life along several dimensions.
  - examples
  - physical function,
  - social function,
  - general health and well-being, and
  - life satisfaction.

Cyclical relationship between Outcomes, Pharmacoeconomics and Pharmaceutical Care



TYPES OF OUTCOMES

1. Positive versus Negative outcomes
2. Intermediate **versus** final outcomes

Positive versus Negative Consequences

- These consequences (outcomes) can be further categorized as positive or negative.
- An example of a positive outcome is a desired effect of a drug (efficacy or effectiveness measure), possibly manifested as
  - Cases cured,
  - Life-years gained, or
  - Improved health-related quality of life (HRQOL).

Outcomes continued…

- Because all drugs have **adverse effects**, negative consequences also can occur with their use.
- A negative outcome is an undesired or adverse effect of a drug, possibly manifested as a
  - treatment failure,
  - an adverse drug reaction (ADR),
  - a drug toxicity, or
  - even death.

OUTCOMES CONTINUED…

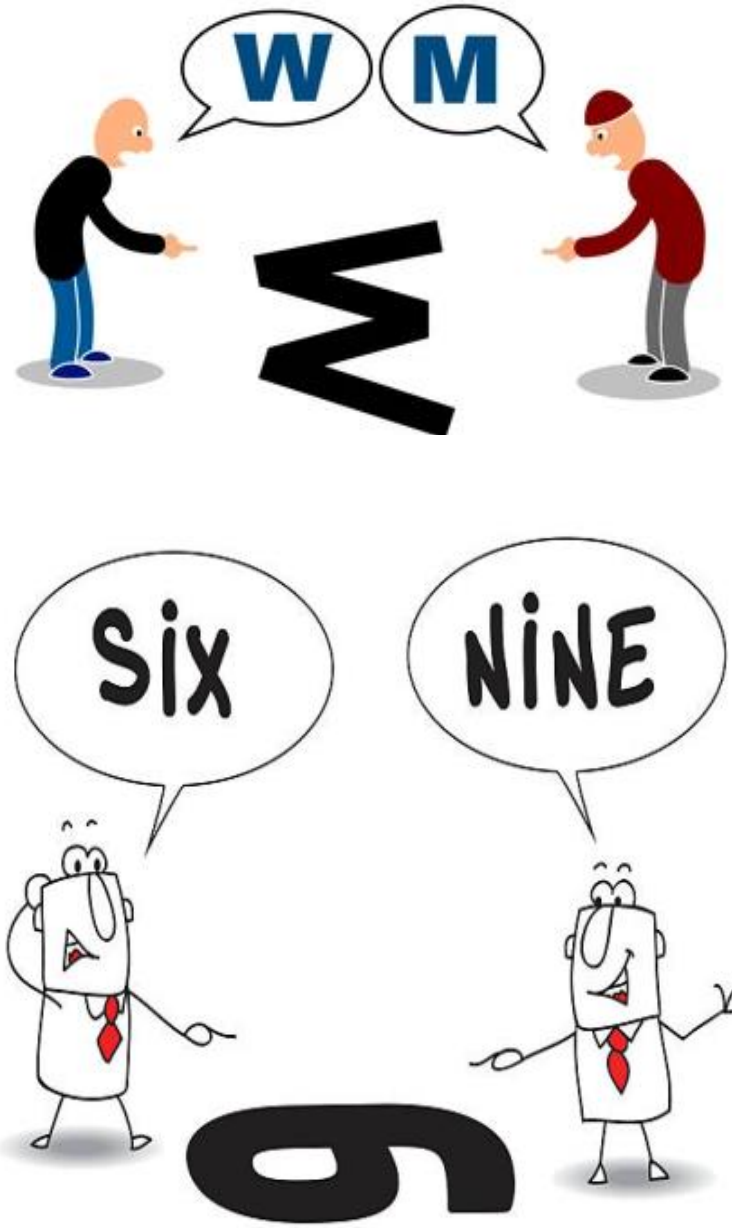
- Pharmacoeconomic evaluations should include assessments of both types of outcomes.
- Evaluating only positive outcomes can be misleading because of the potential detriment and expense associated with negative outcomes.
- Thus the balancing of positive and negative consequences is important in any pharmacoeconomic evaluation.

Intermediate and Final Consequences

- Consequences also can be discussed in terms of intermediate and final outcomes.
- For example, achieving a decrease in low-density lipoprotein cholesterol levels with a lipid-lowering agent is an intermediate consequence that can serve as a proxy for a more final outcome such as a decrease in myocardial infarction rate.
- Intermediate consequences are used commonly in clinical and pharmacoeconomic analyses as proxies predictive of final outcomes because their use reduces the cost and time required to conduct a trial.
- Final Outcomes are long-term effects of a program or treatment alternative. Eg. Decreased MI

PERSPECTIVES

- The perspective of a pharmacoeconomic evaluation is paramount because the **study results** will be highly dependent on the **perspective selected**.
- Assessing costs and consequences—the value of a pharmaceutical product or service—depends heavily on the perspective of the evaluation.
- Picture – who is correct?



PERSPECTIVES CONTINUED….

- A pharmacoeconomic evaluation can assess the value of a product or service from single or multiple perspectives.
- However, clarification of the perspective is critical because the results of a pharmacoeconomic evaluation depend heavily on the perspective taken.
- Once the perspective is clear, a full evaluation of the relevant costs and consequences can begin.
- Again, perspective is critical because the value placed on a treatment alternative will depend heavily on the point of view taken.

PERSPECTIVE

- The "point of view" considered in economic analyses influences the outcomes and costs considered to be most relevant.
- Common perspectives include:
  - Provider
  - Patient
  - Payer
  - Society

1. Patient Perspective

- Patient perspective is paramount because patients are the **ultimate consumers** of healthcare services.
- **Costs,** from the perspective of patients, are essentially what patients pay for a product or service—that is, the portion not covered by insurance.
- **Consequences**, from a patient's perspective, are the clinical effects, both positive and negative, of a program or treatment alternative.
- For example, various costs from a patient's perspective might include insurance copayments and out-of-pocket drug costs, as well as indirect costs, such as lost wages.
- This perspective should be considered when assessing the impact of drug therapy on quality of life or if a patient will pay out-of-pocket expenses for a healthcare service.

2. Provider Perspective

- Costs from the provider's perspective are the actual expense of providing a product or service, regardless of what the provider charges.
- Providers can be hospitals, or private-practice physicians.
- From this perspective, direct costs such as drugs, hospitalization, laboratory tests, supplies, and salaries of healthcare professionals can be identified, measured, and compared.
- However, indirect costs can be of less importance to the provider.
- When making formulary management or drug-use policy decisions, the viewpoint of the healthcare organization should dominate.

Sidebar: Pharmacoeconomic Controversy

- Surprisingly few providers are prepared to identify and measure their true economic costs.
- Charge data may be more readily available but usually are not reflective of the true costs of healthcare.
- Thus it can be challenging to translate charges into actual costs. A cost-to-charge ratio can be useful in many instances.
- Additionally, a common proxy used for costs of medications is average wholesale price (AWP).
- However, realistically, there are no providers actually paying AWP for their drugs, and AWP therefore is not an accurate proxy for drug-cost data.

3. Payer Perspective

- Payers include insurance companies, employers, or the government.
- From this perspective, costs represent the charges for healthcare products and services allowed or reimbursed by the payer.
- The primary cost for a payer is of a direct nature. However, indirect costs, such as lost workdays **(absenteeism),** being at work but not feeling well and therefore having lower productivity **(presenteeism),** also can contribute to the total cost of healthcare to the payer.
- When insurance companies and employers are contracting with healthcare organizations or selecting healthcare benefits for their employees, then the payer's perspective should be employed.

4. Societal Perspective

- The perspective of society is the **broades**t of all perspectives because it is the only one that considers the benefit to society as a whole.
- Theoretically, all direct and indirect costs are included in an economic evaluation performed from a societal perspective.
- Costs from this perspective include patient **morbidity and mortality and the overall costs of giving and receiving medical care.**
- An evaluation from this perspective also would include all the important consequences an individual could experience.
- In countries with nationalized medicine, society is the predominant perspective.

Sidebar: Pharmacoeconomic Controversy

- Controversy surrounds the issue of study perspective.
- Many researchers and academicians assert that society is the only relevant and the most appropriate perspective from which to conduct a pharmacoeconomic analysis.
- However, these studies can be **very resource-intensive in terms of time and money.**
- Further, organizations may need **to focus solely from their own perspectives** to obtain the data necessary to inform timely decision making.

How Can PE Enhance health care Practice?

- PE is an aid to decision making with strong potential to:
  - Mitigate the influence of marketing
  - Help set practice priorities
  - Medicare plans to decrease pay-out to stem tide of budget deficit
  - Statistically more likely to be responsible for better success in clinical care by eliminating poor/ unnecessary care
  - Ethical framework -Fidelity to individual patients

In general, questions that PE may help to address are as follows:

1. What drugs should be included on the hospital formulary?
2. What is the best drug for a particular patient?
3. What is the best drug for a pharmaceutical manufacturer to develop?
4. Which drug delivery system is the best for the hospital?
5. How do two clinical pharmacy services compare?
6. What is the cost per quality year of life extended by a drug?
7. Will patient quality of life be improved by a particular drug therapy decision?
8. What is the best drug for this particular disease?
9. What are the patient outcomes of various treatment modalities?

Individual Reading Assignment

- What is market failure in healthcare?
- What are the causes of market failure in healthcare?
- What are the possible solutions for market failure in healthcare?

End of Chapter 2

Thank you